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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,041	12/22/2006	Soili Peltonen	0365-0670PUS1	4395

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
CHAN, HENG M	

ART UNIT	PAPER NUMBER
1728	

NOTIFICATION DATE	DELIVERY MODE
05/17/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/573,041	PELTONEN ET AL.	
	Examiner	Art Unit	
	HENG M. CHAN	1728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-52 and 64-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-52 and 64-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/8/2010 has been entered. Supplemental amendments and arguments filed on 3/10/2011 have been acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 31-52 and 64-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 31 recites "C1-C6 alkane" as a non-solvent. However, the specification does not support such a limitation.

Claims 32-52 and new claims 64-66 are rejected for depending on claim 31 with the new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 31-52 and 64-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites that the solution of starch derivative and a mixture of a solvent and water is brought into contact with a non-solvent. However, the fate of the non-solvent thereafter is unclear. The non-solvent should be a component in the dispersion which is formed from the solvent and the water and the liquid phase comprising both the solvent and the water. It is unclear if the non-solvent is separated from the precipitate just like the water. For examination purposes, the non-solvent is treated as a component in both the dispersion and the liquid phase and is removed from the precipitate.

Claims 32-52 and 64-66 are rejected for depending on the indefinite claim 31.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 31-40, 42-48, 50-52, and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,562,459 to Bengs et al., in view of US 6,617,449 to Tanaka and US 5,693,279 to Feuer et al.

Regarding claims 31, 36, and 37, Bengs et al. teach a method of manufacturing a starch-based material suitable for being used as, for example, a filler, comprising:

dissolving a starch derivative, e.g. a starch ester, in a solvent or a mixture of a solvent and aqueous solutions so that a solution comprising the starch derivative is formed (column 5, lines 13-25),

bringing the solution into contact with a precipitant or a non-solvent, e.g. a mixture of water and alcohol, in which the starch derivative is not dissolved so as to precipitate the starch derivative from a dispersion which is formed from the solvent, the water, and the non-solvent, so that a precipitate comprising the starch derivative and a liquid phase comprising the solvent, the water, and the non-solvent are formed, and

removing the precipitate from the liquid phase to obtain the starch-based filler (Claim 1; abstract; column 3, lines 6-24 and 38-42; column 5, lines 13-25 and 33-37; column 8, lines 24-25; Example 1).

Bengs et al. do not expressly teach removing the solvent from the liquid phase and separating and recovering the precipitate from the water and the non-solvent.

However, it would have been obvious to one of ordinary skill in the art at time of invention to have separated the precipitate from the liquid phase in a batch manner or continuously, because the court held the claimed continuous operation would have been obvious in light of the batch process of the prior art and so that the reverse must be true. See MPEP 2144.04. Also, changing the order of steps in a process does not impart patentability in the absence of new or unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results). See MPEP § 2144.04.

Bengs et al. do not expressly teach that the starch derivative has a glass transition point of 60°C to 350° as per claim 31 or at least 100°C as per claim 36.

Tanaka also relates to starch esters made from esterified or acylated starch compounds and suitable as base polymer of biodegradable plastic articles and other articles and teaches that the starch esters have a glass transition point of 140°C or less, preferably 130°C or less. The lower limit of the glass transition point shall be usually 80°C, preferably 100°C (column 2, lines 52-56).

It would have been obvious to one of ordinary skill in the art at time of invention to have used any conventionally known starch esters such as those of Tanaka in the method of Bengs et al., in order to obtain the starch-based material for applications such as filler in particular for biodegradable polymers or industrial polymers (Bengs

column 8, lines 24-25; Tanaka column 1, lines 8-33). Furthermore, a *prima facie* case of obviousness exists in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art". *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05[R-5].

Finally, Bengs et al. and Tanaka do not expressly teach that the solvent is ketone.

Feuer et al. also relate to starch acetate that has been known to be desirable and biodegradable reactants for the development of plastics and other products and teach that starch acetate is soluble in a mixture of acetone and water (abstract; column 1, lines 30-33; column 5, lines 48-57).

It would have been obvious to one of ordinary skill in the art at time of invention to have used a solvent such as acetone to dissolve the starch ester or starch acetate of Tanaka in the method of Bengs et al., motivated by the fact that Bengs et al. teach that any suitable solvent can be used to dissolve the starch ester derivative (column 5, lines 14-25) and so the skilled artisan would have used a conventional solvent like acetone and obtained an expected solution of starch ester.

Regarding claim 32, Bengs et al. teach rapidly dissolving 1g of starch in 5ml of the solvent in Example 1b, which suggests that no excess solvent or just enough solvent is used to dissolve the starch derivative.

Regarding claims 33 and 34, Bengs et al. teach that the total concentration of the starch derivative in the solvent may vary within wide limits according to demand. It is

preferably in a range from 0.02 g (starch derivative)/ml (solvent) to 1.0 g/ml, in particular from 0.05 g/ml to 0.8 g/ml and particularly preferably from 0.3 g/l to 0.6 g/l (column 5, lines 26-32). Bengs et al. teach adding 30 g of starch to 500 ml of solvent, which would be about 22 wt.% (Example 1).

Bengs et al. do not expressly teach that the concentration of the starch derivative in the solution is at least 1% by weight, preferably approximately 10-30% by weight.

However, it would have been obvious to one of ordinary skill in the art at time of invention to have varied the concentration of the starch derivative in the solution according to demand as suggested by Bengs et al. and optimized the concentration through routine experimentation. A *prima facie* case of obviousness exists in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art". *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05[R-5].

Regarding claim 35, Bengs et al. teach a concentration of starch that is overlapping with the claimed ranges of concentrations (see rejections of claims 33 and 34 above).

Bengs et al. do not expressly teach that the viscosity of the solution is 1-5 times the viscosity of water.

However, it would have been obvious to one of ordinary skill in the art at time of invention to have realized that the viscosity of a starch solution depends on the concentration of the starch and because Beng et al. teach an overlapping range of concentration of starch in the solution, the viscosity of the same solution necessarily

follows the concentration. Therefore, the viscosity of the solution of Beng et al. is expected to overlap with the claimed range.

Regarding claims 38 and 39, Tanaka teaches that the starch ester can esterified or acylated by replacing hydrogens in reactive hydroxyl groups with, for example, C_{2-4} short-chain acyl groups (abstract). A C_2 acyl group would give a starch acetate.

Regarding claim 40, Bengs et al. teach that the starch can be chemically modified by esterification and/or etherification of a hydroxyl group (column 3, lines 38-42). That is, the starch ester can also be hydroxyl alkylated.

Regarding claim 42, Bengs et al. teach that the precipitate is separated from the liquid phase.

Bengs et al. do not expressly teach that after the solvent is removed, the precipitate separated from the liquid phase does not contain such amount of solvent residues that the solvent can be detected with a 300 MHz NMR device.

However, absent of such a specific teaching about the amount of solvent residues would clearly suggest to one of ordinary skill in the art at time of invention that there was not any residual solvent in the precipitate separated from the liquid phase. Furthermore, the skilled artisan would have not expected any residual solvent after extensive purification and drying as described in Example 1.

Regarding claim 43, a solvent such as acetone can be completely mixed with a non-solvent like water.

Regarding claims 44-46, Bengs et al. teach that the solvent/ precipitant(non-solvent) ratio is preferably selected within a range from 1:1000 to 1:4 (part of

solvent/parts of precipitant) preferably 1:100 to 1:10 and in particular 1:70 to 1:30 (column 5, lines 38-41). The ratio is usually based on mass. A *prima facie* case of obviousness exists in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art". *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05[R-5].

Regarding claims 47 and 52, Bengs et al. teach introducing the solution into the precipitant with rapid mixing, or stirring, i.e. in a turbulent condition, to form spherical microparticles (abstract; column 5, lines 47-51; Example 1b).

Regarding claim 48, Bengs et al. teach that the particles may have average diameters (number average) of from 1 nm to 100 µm, preferably 100 nm to 10 µm and particularly preferably 1 µm to 5 µm (column 7, lines 38-41). A *prima facie* case of obviousness exists in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art". *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05[R-5].

Regarding claims 50 and 51, Bengs et al. teach that the order in which the starch derivative solution and the precipitate or non-solvent are combined, for example whether the precipitant is added to the solvent or vice versa, is unimportant in this context (column 5, lines 48-51).

Bens et al. do not expressly teach that the solution is added, while mixing, to the non-solvent so as to produce a coral-like, porous pigment with the claimed particle size and pore size.

However, it would have been obvious to one of ordinary skill in the art at time of invention to have added the solution, while mixing, to the non-solvent as suggested by Bengs et al. and obtained the claimed coral-like, porous pigment with the claimed particle size and pore size because the skilled artisan would have expected the same product from the same method, absent convincing evidence to the contrary.

Regarding claims 64-66, Bengs et al. teach that the precipitant or non-solvent comprises water or a mixture comprising water and ethanol (column 5, lines 33-37). The latter reads on claim 66 as the non-solvent comprises ethanol.

5. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bengs et al., Tanaka, and Feuer et al. as applied to claim 31 above, in view of US 4,011,392 to Rudolph et al.

Regarding claim 41, Bengs et al. do not expressly teach that the degree of substitution of the ester groups of an ester functioning as the starch derivative is chosen in a way that the starch derivative is fundamentally insoluble in the non-solvent.

Rudolph et al., who also relate to starch esters, teach that the degree of substitution is a critical factor in determining the starch esters characteristics and performance. In general, the hydrophobicity of the starch polymer increase substantially as the degree of substitution increases. This may be illustrated by the solubility

properties of the starch polymer which changes from water-soluble, organic-insoluble at low degrees of substitution to water-insoluble, organic-soluble at high degrees of substitution (column 5, lines 11-19).

Therefore, it would have been obvious to one of ordinary skill in the art at time of invention to have appropriately chosen a degree of substitution for the starch esters so that the starch derivative is substantially insoluble in the non-solvent in the method provided by Bengs et al., motivated by the fact that the skilled artisan would have appreciated making the starch derivative insoluble in the non-solvent in order for it to be precipitated and the skilled artisan would have done so by manipulating the degree of substitution of starch esters as suggested by Rudolph et al.

6. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bengs et al., Tanaka, and Feuer et al. as applied to claim 47 above, in view of US 4,716,186 to Portnoy et al.

Regarding claim 17, Bengs et al. teach that the starch derivative is precipitated with a precipitate or non-solvent, separated, and recovered (Example 1).

Bengs et al. do not expressly teach that fine particles dispersed in the liquid phase are precipitated by salting out after the starch derivative is precipitated from the solution.

Portnoy et al. also relate to starch derivatives and teach that the starch derivative can be separated from impurities such as inorganic salts by for example, salting out (column 1, lines 51-63).

Therefore, it would have been obvious to one of ordinary skill in the art at time of invention to have further precipitated fine particles from the liquid phase after separating the starch derivative in the method provided by Bengs et al., motivated by the fact that the skilled artisan would have appreciated further extract the starch derivative from the liquid phase and possibly getting rid of impurities as suggested by Portnoy et al.

Response to Arguments

7. Applicant's arguments with respect to claim 31 have been considered but are moot in view of the new ground(s) of rejection. In the remarks filed on March 1, 2010 and December 8, 2010, Applicants had pointed to earlier amendments to claim 31 reciting a glass transition point of 60℃ to 350℃, a mixture of a solvent and water as the solvent, and water being a non-solvent and argued about considerable advantages of the products due to the starch derivative and the water non-solvent of the claimed invention. In the remarks filed on March 10, 2011, Applicants further indicated that the solvent is ketone and the non-solvent is at least one selected from the group consisting of water, C_1-C_6 alkanol and C_1-C_6 alkane and argued that the present invention avoids excess solvent while Bengs teaches dissolving the starch derivative excessively.

The Examiner has applied a primary reference to Bengs who teaches a method of making a starch-based material such as filler, in particular for biodegradable polymers or industrial polymers, by dissolving a starch derivative like starch ester in a mixture of solvent and water and precipitating it with a water non-solvent (column 1, liens 47-54; column 5, lines 13-25 and 33-37). Tanaka teaches starch esters having an

overlapping range of glass transition point as claimed and the skilled artisan would have used the starch esters of Tanaka in the method of Bengs to produce the biodegradable products because Tanaka recognizes that the starch ester is a base polymer for biodegradable start-based products like plastic (column 1, lines 8-33). Feuer further supplements Bengs and Tanaka by teaching that starch acetate, which is a starch ester also mentioned in Tanaka, is soluble in acetone and water (column 5, lines 52-55). The resulting product from Bengs, Tanaka, and Feuer would have had the considerable advantages acclaimed by Applicants in the previous responses. Regarding the argument about the amount of solvent, it is noted that a minimum amount of solvent is not claimed until claim 32 and the claims do not specifically define what is considered minimum or excess. Bengs' solution can be considered to comprise a minimum amount of solvent since a solution is produced as claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HENG M. CHAN whose telephone number is (571)270-5859. The examiner can normally be reached on Monday to Friday, 9:30 am EST to 6:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer K. Michener can be reached on (571)272-1424. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer K. Michener/
Supervisory Patent Examiner, Art Unit 1728

/HENG M CHAN/
Examiner, Art Unit 1728